



Radiology Associates of Central Florida

General Radiology • Vascular & Interventional Radiology • Computerized Tomography
ACR Accredited Mammography • Magnetic Resonance Imaging (MRI) • Ultrasound • Stereotactic Needle Core Breast Biopsy

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Suite 510
(352) 753-4115

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**Leesburg Regional
Medical Center
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March 2, 2000

Docket No. 99D-4910, Dockets Management Branch
Division of Management Systems & Policy
Office of Human Resources & Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA - 305)
Rockville, MD 20852

RE: CFR 900.12 (b)(8)(i)

To Whom It May Concern:

I am writing this letter in behalf of Radiology Associates of Central Florida. We are a group of 11 Radiologists who perform approximately 20,000 mammograms each year.

We would like to speak against the planned requirement for fine adjustment compression controls operable from both sides of the patient.

We are very proud of the fact that all of our facilities are accredited and, of course, all of the MQSA rules are followed to a tee.

If this new proposed requirement is put into force, we will have to replace five of the seven mammographic machines that we currently either own or utilize. As far as I am aware, there is no add-on equipment that is available to make these mammographic machines compliant with the proposed MQSA regulation.

Two of our machines do have manual fine adjustments, but in reviewing our films I see no significant difference in the imaging. All of our equipment, as mentioned, has been able to pass the high standard already set.

I would appreciate if you would consider our comments in reference to the above.

Sincerely yours,

Michael S. Levine, M.D.
Supervising Radiologist for Mammography
Radiology Associates of Central Florida
Lake Medical Imaging and Breast Centers

MSL/yw

CC: Mary E. Swain, M.D.
Chairman, Mammography Committee
President, Florida Radiological Society

99D-4910

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